NASA CR 65537

APOLLO PULMONARY GAS COLLECTION ASSEMBLY AND ASSOCIATED EQUIPMENT DEVELOPMENT PROGRAM

FINAL REPORT

Contract No. NAS 9-5514

Melpar Job No. 5768.00100

Submitted to

NASA MANNED SPACECRAFT CENTER

CREW SYSTEMS DIVISION

Houston, Texas 77058

GPO PRICE $ _____

CFSTI PRICE(S) $ _____

Hard copy (HC) 3.50

Microfiche (MF) .75

ff 653 July 65

Submitted by

MELPAR, INC.
7700 Arlington Boulevard
Falls Church, Virginia 22046

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1. INTRODUCTION

This document is submitted as the Final Report on Contract No. NAS 9-5514 with NASA Manned Spacecraft Center, Crew Systems Division, Houston, Texas.

The purpose of the Apollo Pulmonary Gas Collection Assembly, hereinafter referred to as the Gas Collection Assembly, and the associated equipment (figure 1) is to collect expired respiratory gas from flight crew members under conditions of rest, exercise, and maximum voluntary ventilation in order that quantitative data may be obtained relevant to the physiological status of the flight crew member's pulmonary systems during manned space flight missions.

The objective of gas collection assembly development program was the design, development, fabrication, and flight qualification of a pulmonary gas collection assembly required for the conduct of approved Project Apollo medical in-flight experiments. The gas collection system was designed to be used to perform Medical Experiment M-20 in conjunction with the gas volume meter that is being provided for Medical Experiment M-19. (See figure 2.)

To achieve the objectives of the contract, the program progressed through three stages: (1) Design and Development, (2) Flight Qualification, and (3) Production.

During design and development, preliminary design of the system was completed, a materials-selection study was done, mockups were supplied of both the storage configuration and the operational configuration, and

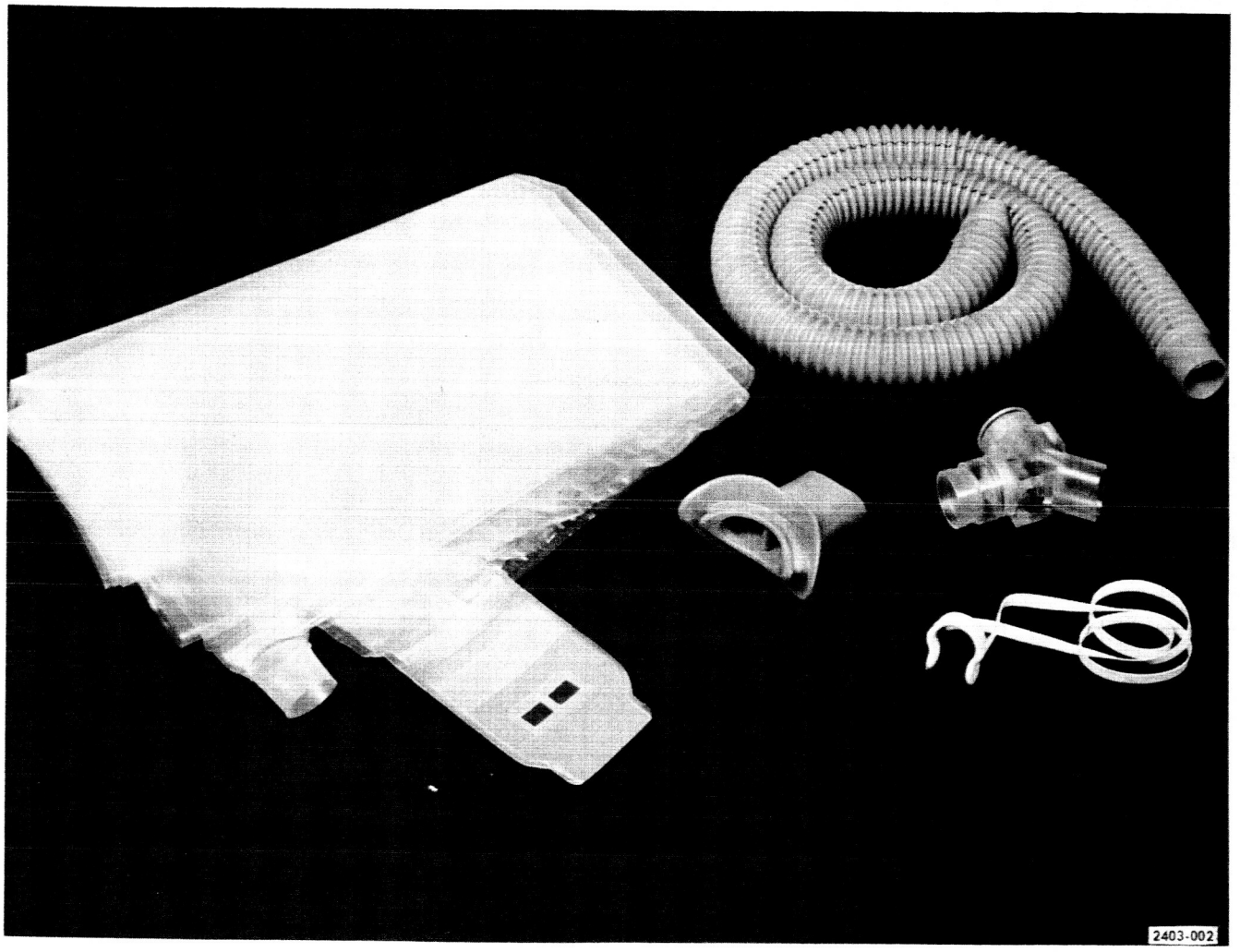


Figure 1. Pulmonary Gas Collection Assembly and Associated Equipment

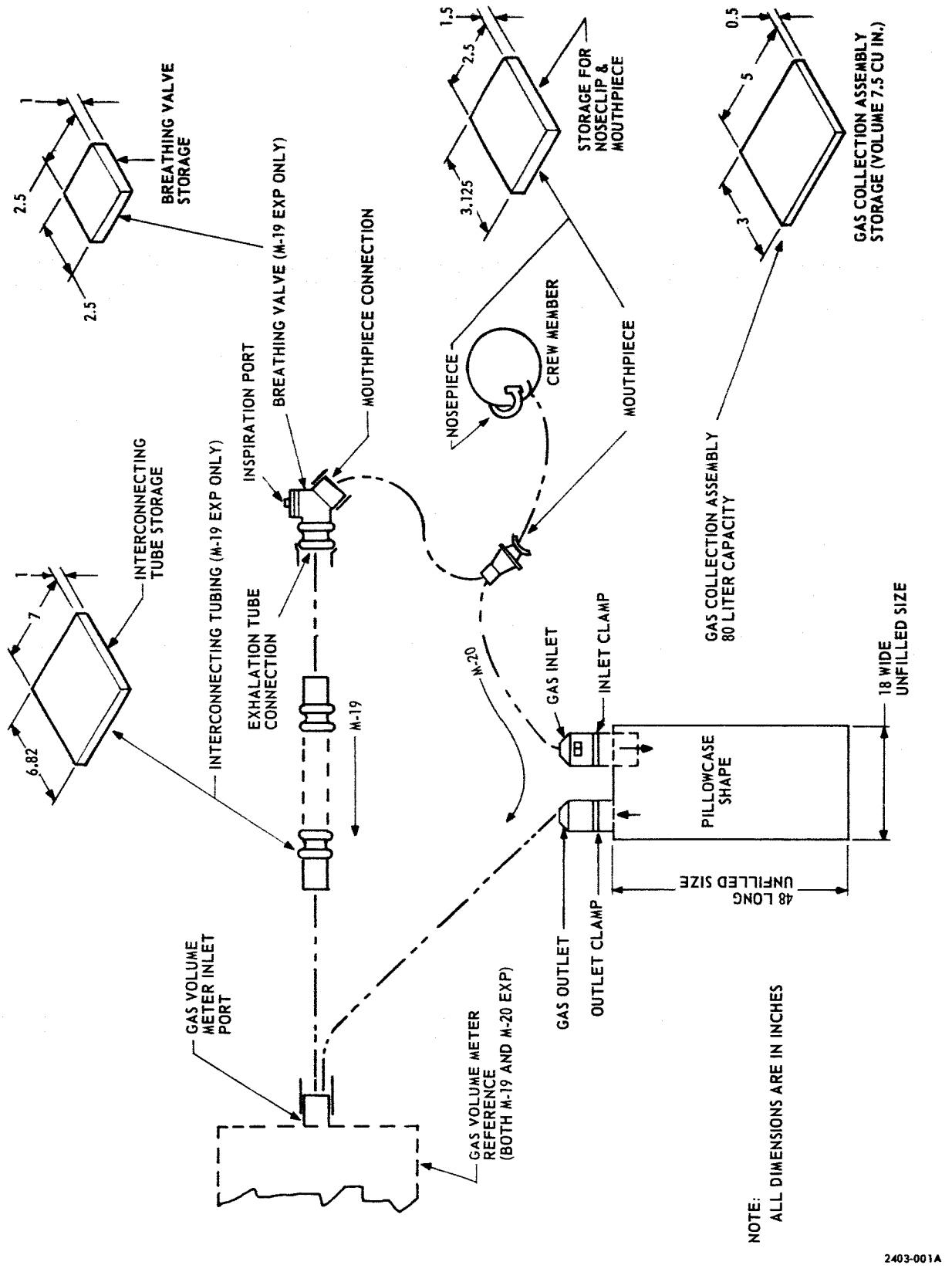


Figure 2. Pulmonary Gas Collection Assembly and Associated Equipment Flow Diagram

deliverable prototypes were fabricated for evaluation in an extensive design-approval testing program. (A detailed description of the Design Approval Testing and Test Data is attached as appendix A to this report.) A reliability and quality assurance program was also conducted during this phase.

The second part of this program was concerned with qualification tests performed on the first production units in order to demonstate the suitability of the items for their intended use and their ability to withstand selected environmental stresses. A summary of the test procedures and results for the pulmonary gas collection assembly and associated equipment items subjected to the qualification tests is included in appendix "B" to this report.

The last stage of the program consisted of the procurement and manufacture of deliverable operational and training units and the flight and backup units. Acceptance testing of the production units in accordance with approved test procedures was also a part of this phase.

2. DESCRIPTION OF EQUIPMENT

The gas collection assembly and associated equipment consists of the following items:

a. Pulmonary gas collection assembly

b. Nose clip

c. Mouthpiece

d. Breathing valve

e. Interconnecting tubing

2.1 Configuration

The gas collection assembly consists of two distinct configuration arrangements identified as the storage configuration and the operational configuration. Specifications for these two arrangements are delineated under section 3, Performance and Design Specifications.

Gas Collection Assembly (see figure 3): The gas collection assembly is a pillowcase-shaped plastic (2-mil) container. The assembly has a capacity of 80 liters of expiratory gases at zero differential pressure across the walls of the bag. It is basically patterned after the Douglas bag, commonly used in respiratory physiological investigative work.

Gas Inlet and Outlet: The gas inlet connection of the gas collection assembly will interface with the mouthpiece. With the outlet port clamp closed, the inspiratory valve permits the expiration gases to be channeled directly into the gas collection bag when the inlet clamp is open or to be exhausted into the spacecraft crew compartment when the inlet clamp is closed. The gas outlet port provides the means of exhausting the collected

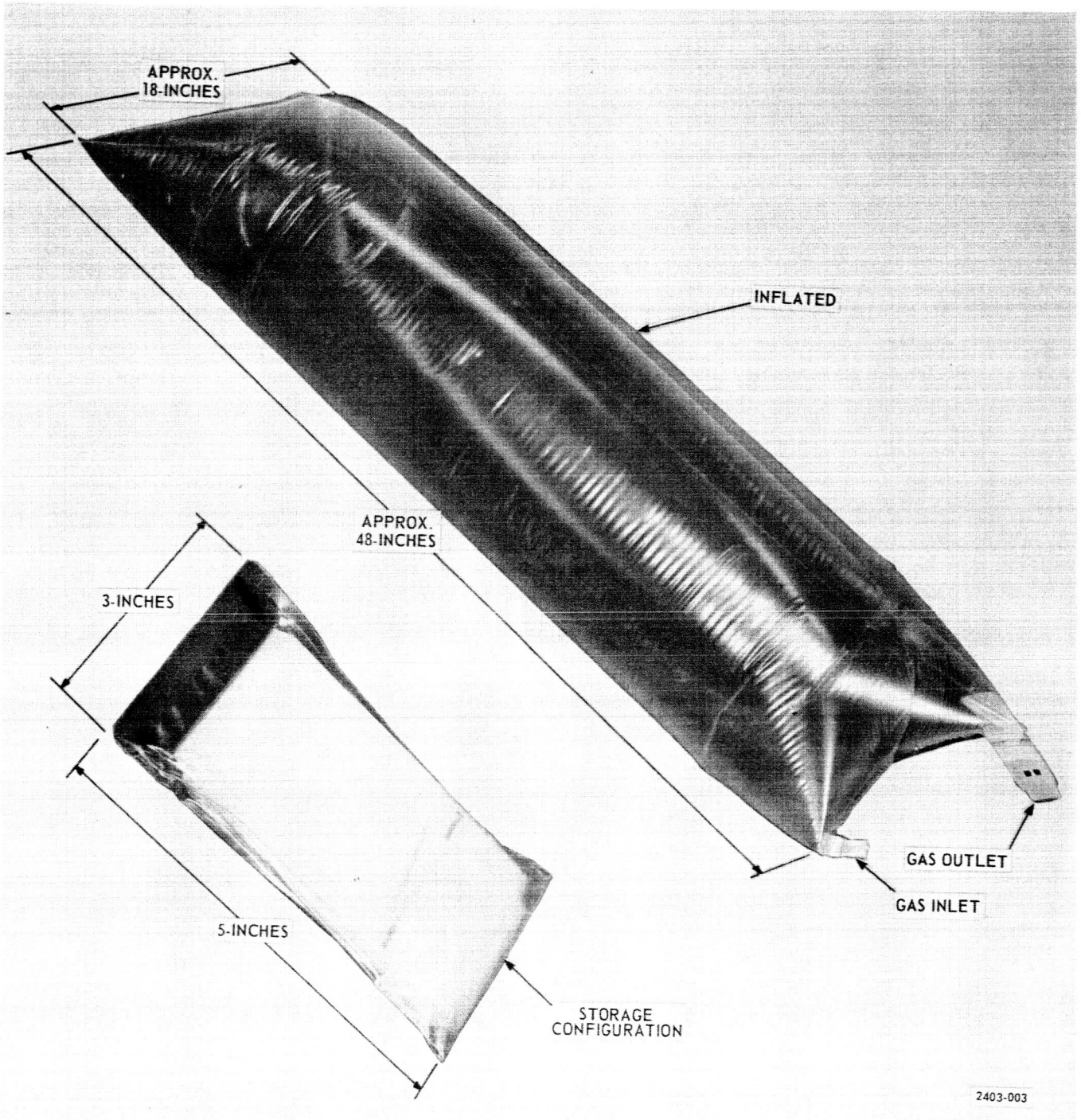


Figure 3. Pulmonary Gas Collection Assembly

gases into the gas meter (reference Medical Experiment No. M-19) during the performance of Medical Experiment No. M-20.

The inlet and outlet valving assemblies are an intrinsic part of the gas collection assembly and provide positive separation of inspiratory and expiratory gas-flow pathways. A positive clamping arrangement is provided in both the gas inlet-outlet ports as part of this assembly.

2.2 Associated Equipment

The associated equipment is shown in figures 4, 5, and 6.

Nose Clip (see figure 4): The function of the nose clip is to close the nostrils of the exercising crewmember while Medical Experiments Nos. M-19 and M-20 are being performed. The nose clip functions in a positive, spring-actionlike manner without producing undue discomfort.

Mouthpiece (see figure 4): The mouthpiece is designed for comfort in use and has a minimum of leakage. It interfaces with the breathing valve during the performance of Medical Experiment No. M-19 and with the gas collection assembly during Medical Experiment No. M-20.

Breathing Valve (see figure 5): The breathing valve is connected between the mouthpiece and the interconnecting tubing during Medical Experiment No. M-19. The breathing valve has an inspiration port to provide cabin atmosphere to the crewmember during the experiment.

Interconnecting Tubing (see figure 6): The interconnecting tubing is 32 inches in length; it is lightweight and flexible due to the corrugated design. The interconnecting tubing is used during Medical Experiment No. M-19 and provides the interface between the gas volume meter and the breathing valve.

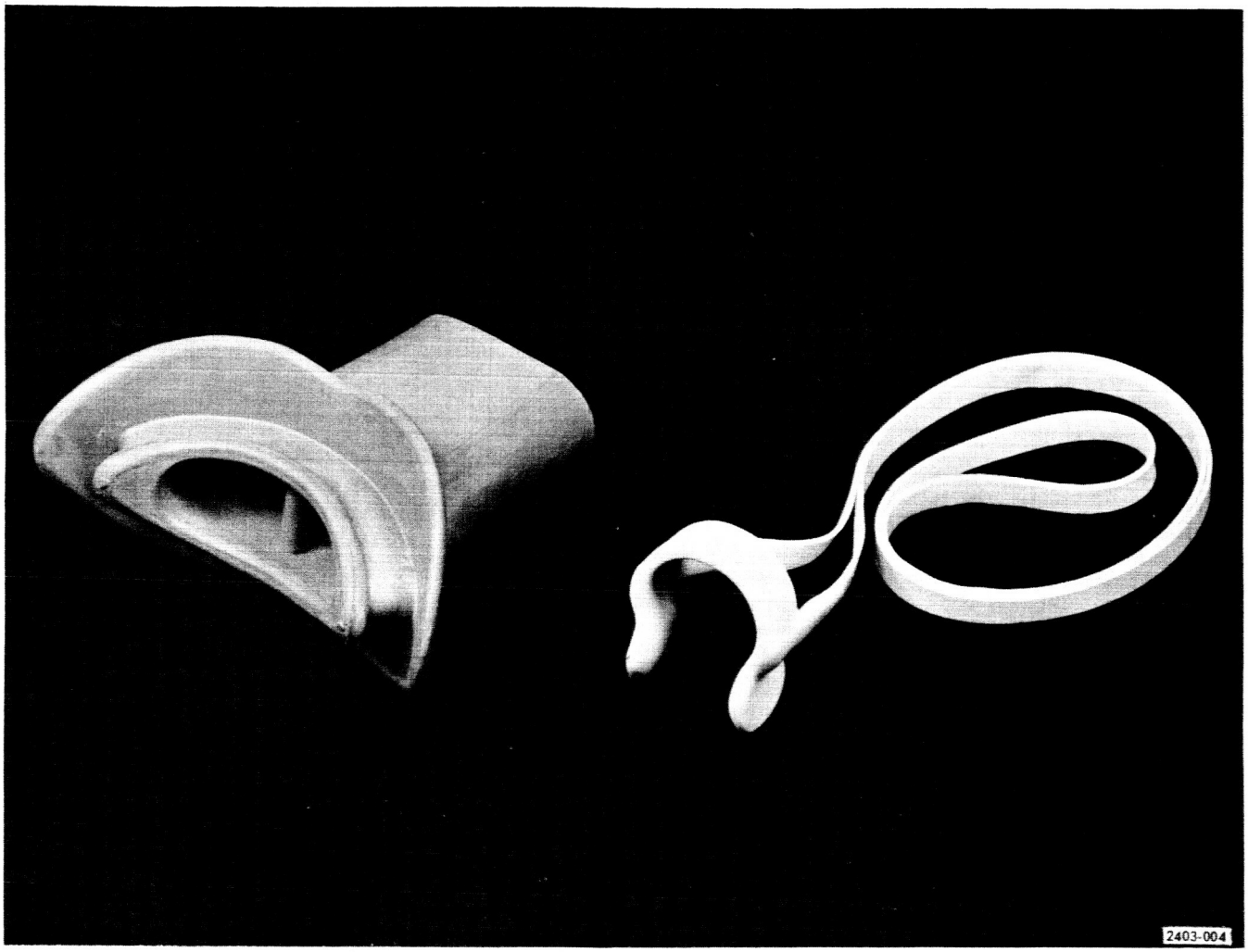


Figure 4. Nose Clip and Mouthpiece

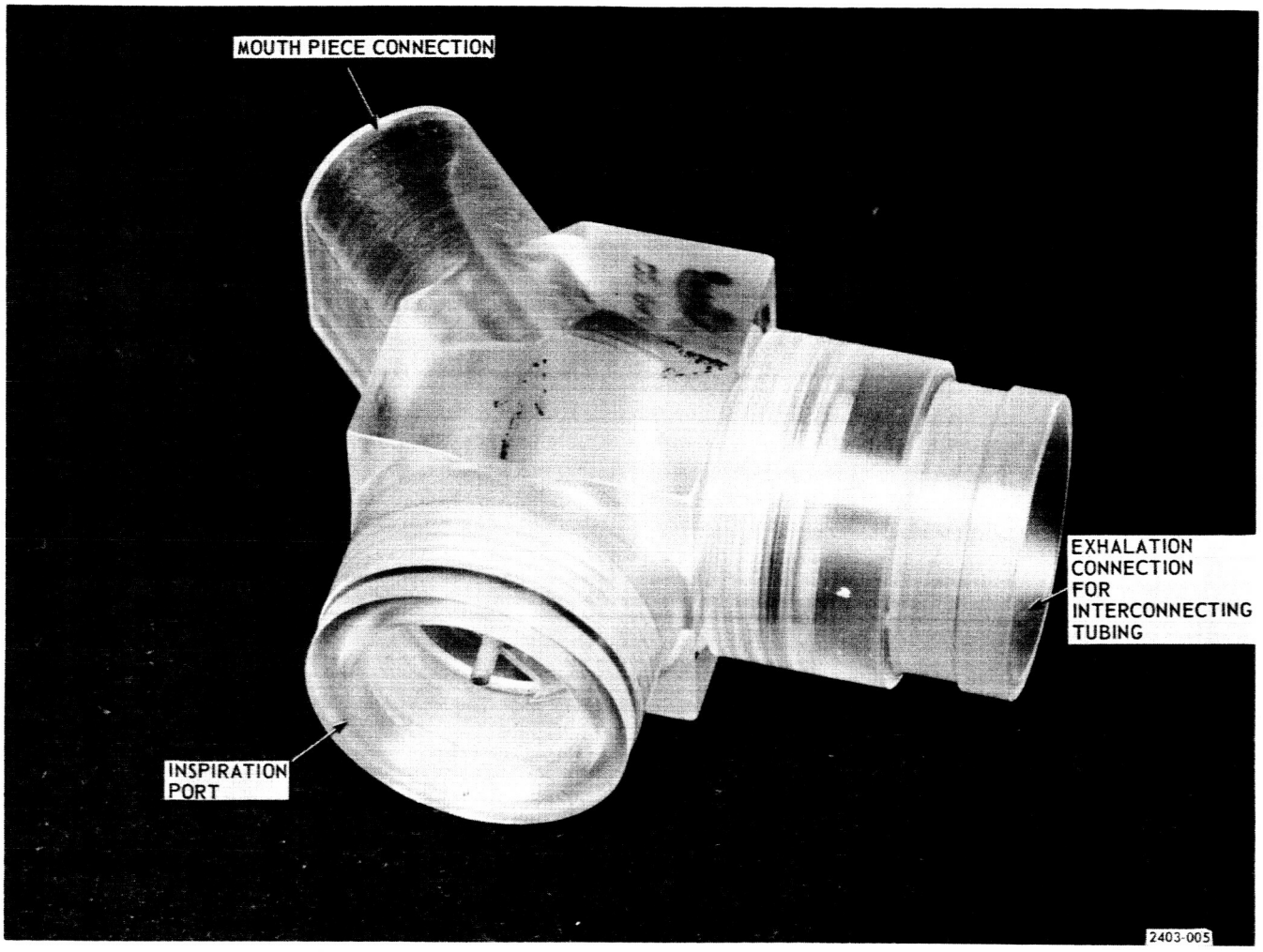


Figure 5. Breathing Valve

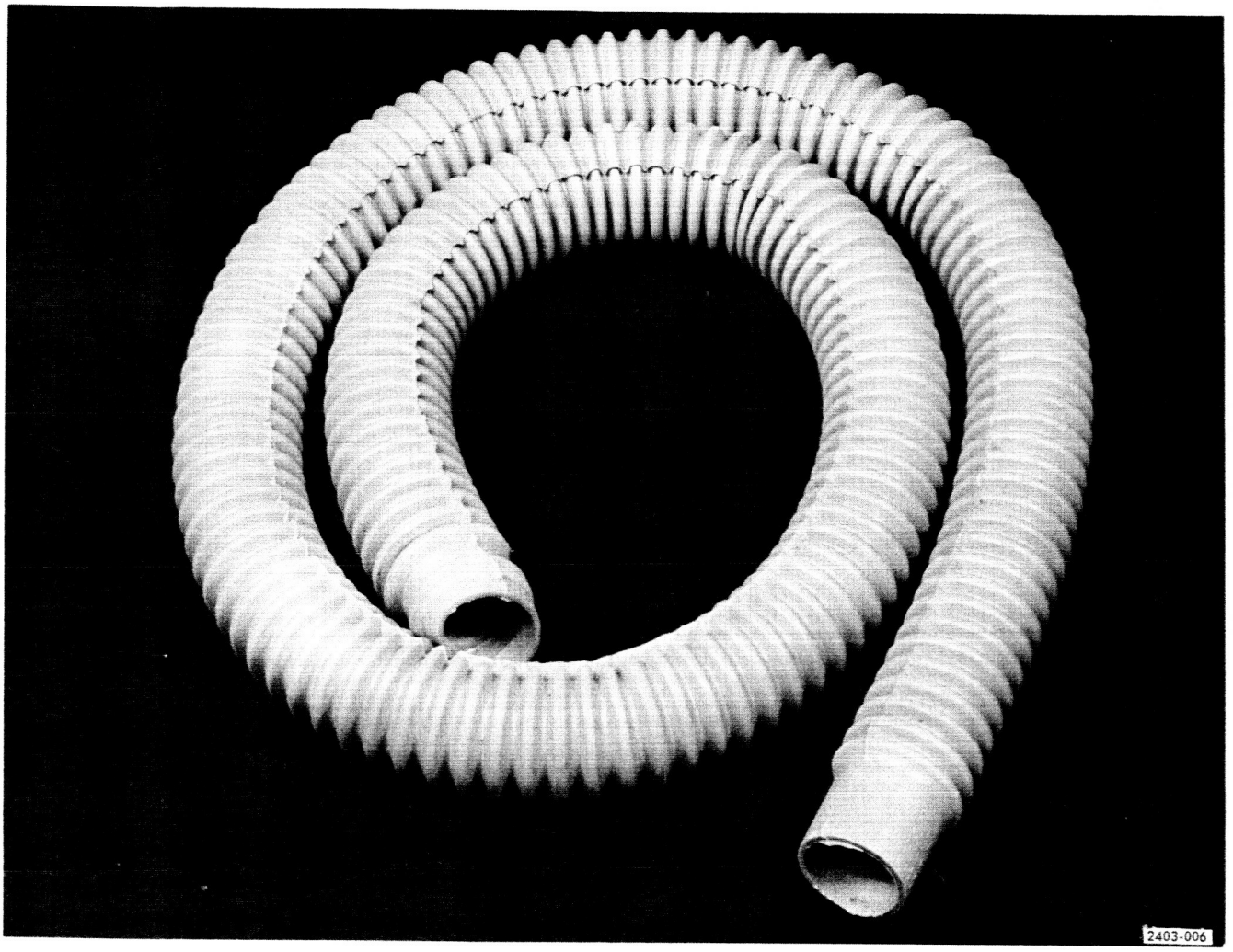


Figure 6. Interconnecting Tubing

2.3 Hardware Definitions

The following types of equipment were supplied:

Envelope Mockups: These mockups showed the conceptual shape and size of each individual end item but did not include accurate weight and center of gravity properties. Mockups of both the storage and operational configurations were supplied.

Prototypes: These were flight-qualifiable units of all end items, identical in design and configuration to the flight units, and complete with accessories.

Qualification Test Units: These were flight-qualifiable units, selected from the first production units.

Flight and Backup Units: These units were the flight items and conformed to all stated requirements and specifications.

Operations and Training Units: These units were complete sets of all end items for use in crew-training facilities. They were in final flight configuration to provide realistic operational and manipulation characteristics and to determine compatibility with other crew equipment and activities.

3. PERFORMANCE AND DESIGN SPECIFICATIONS

3.1 General

This section describes the performance and design requirements for the gas collection assembly and associated hardware for collection of respiratory gases during Project Apollo In-Flight Medical Experiments.

3.2 Configurations

The gas collection assembly consists of two distinct configuration arrangements: storage and operational.

In the storage configuration, the gas collection assembly including valving assembly and clamp is to be compacted into a storage volume as small as possible, not to exceed 7.5 cubic inches, rectangular in shape, and the dimensions not to exceed 0.5 by 3 by 5 inches.

For descriptive purposes only, the storage configuration is separated into initial and subsequent storage subconfigurations. In the initial storage arrangement the collection assembly and associated equipment is packaged in individual plastic overwraps evacuated to an internal absolute pressure of 6 mm of mercury. The packaged units withstand exposure to 5 ± 0.5 psia spacecraft crew compartment oxygen atmosphere as well as decompression without rupture and/or ballooning to a total volume exceeding 23 cubic inches. The packaged units are delivered to NASA-MSC in this configuration.

In the subsequent storage subconfiguration, the packaged units have been opened, used for experimental purposes, and returned to the plastic outer wrap. If subjected to decompression in this configuration, the

package ruptures rather than ballooning out into the crew compartment to a total volume exceeding 30 $in.^3$ as a result of entrapped gases.

The plastic overwrap permits repeated removal and repackaging of the units in a gravity-free environment.

In the operational configuration the gas collection assembly, subsequent to unfolding, contains at least 80 liters of expiratory gases at zero pressure differential across the walls of the assembly.

3.3 Performance Specifications

3.3.1 General

The gas collection assembly and associated hardware are fabricated of lightweight, flexible plastic except in those areas which for proper functioning require reinforcement or rigidity by use of semirigid materials, i.e., breathing valve, nose clip. All materials meet specifications contained herein.

The gas collection assembly requires absolute minimum of flight crew members' time and effort in order to perform Medical Experiment M-20 during space flight missions.

3.3.2 Functional Characteristics

The design of the gas collection assembly is basically patterned after that of the Douglas bag, commonly used in respiratory physiological investigative work. For descriptive purposes, the gas collection assembly can be divided into the main body (gas collection bag), gas inlet and outlet, valving and routing components, and clamping arrangements for containment or routing of the collected gases.

Main Body: The function of the main body is to serve as an expiratory gas collection bag. The main body is strong enough to withstand repeated handling under adverse operational conditions.

Gas Inlet: The gas inlet interfaces with the mouthpiece. It is one inch in length and provides easy, yet gas-tight, mating with the mouthpiece.

Gas Outlet: The main body contains an outlet which when closed permits collection and containment of expiratory gases. When the outlet is connected to the gas meter and opened, the outlet permits the exhaustion of the collected gases through the gas meter. The gas outlet is a minimum of 1 inch in length and allows easy, yet gas-tight, mating with the gas inlet of the gas volume meter for Experiment M-19.

Valving and Routing Components: The valving assembly, which is an intrinsic component of the pulmonary gas collection assembly, provides positive separation of inspiratory and expiratory gas flow pathways. The maximum dead space within the valving arrangement does not exceed 50 ml, excluding dead space of the mouthpiece. The pressure differential across the inspiratory valve does not exceed 1 inch of water pressure at a flow velocity of 400 liters per minute.

The main body of the gas collection assembly contains a selective channeling arrangement in the inlet region which allows the expiratory gases to be channeled either directly into the gas collection bag or to be exhausted into the spacecraft crew compartment.

The selective channeling for the expiratory pathway does not cause a pressure differential between the expiratory gas valve and the interior

of the gas collection bag or the ambient crew compartment atmosphere exceeding a pressure of 0.1 inch of water at flow rates of 400 liters per minute. This pressure-drop specification is applicable to either channel in the unclamped state only.

Leakage Rate: The leakage rate of the complete gas collection assembly, including mouthpiece, valves, channeling, and clamping arrangements, does not exceed 100 ml per hour with the assembly pressurized to 0.2 psia above the ambient pressure. The ambient pressure is 5.0 ± 0.5 psia and the ambient temperature 80°F. The specified leakage rate includes diffusion through the walls of the gas collection assembly when the interior gas content is 90 percent oxygen and 10 percent carbon dioxide and the exterior atmosphere consists of 100 percent oxygen.

3.3.3 Electrical Characteristics

Power Requirements: The gas collection assembly does not require either spacecraft electrical power or self-contained batteries for any phase of its operation and function.

Static Electricity Hazards: The gas collection assembly will not create any static electricity hazards in an environment of 100 percent oxygen at 5 ± 0.5 pounds per square inch absolute pressure, and a relative humidity ranging from 50 to 100 percent.

3.3.4 Interfaces

The operational configuration of the gas collection assembly interfaces with the mouthpiece, nose clip, and the gas volume meter provided for Medical Experiment M-19. These interfaces permit efficient and unimpeded conduct of Medical Experiment M-20 in a gravity-free environment.

3.4 Associated Hardware

The associated hardware for the pulmonary gas collection assembly consists of the following individual end items of this Statement of Work:

a. Nose clip

b. Mouthpiece

c. Breathing valve

d. Interconnecting tubing

3.4.1 Configuration

With the exception of the interconnecting tubing, all associated hardware has identical operational and storage configurations.

Storage Configuration for Nose Clips and Mouthpieces: In the storage configuration, one mouthpiece and one nose clip fits into an assigned storage area with the following maximum dimensions: 3.125 by 2.5 by 1.5 inches. In this configuration each nose clip is stored within the hollow segment of a mouthpiece.

Storage Configuration for Breathing Valves: Each breathing valve is contained within a storage area not to exceed 2.5 by 2.5 by 1.0 inches.

Storage Configuration for Interconnecting Tubing: In the storage configuration, the interconnecting tubing fits into an assigned storage area of 1 by 7 by 6.82 inches.

In the storage configurations, these end items are packaged in individual plastic cover bags.

3.4.2 Performance Specifications for Associated Hardware

The associated hardware end items are fabricated of lightweight materials.

3.4.2.1 Nose Clip: The function of the nose clip is to close the nostrils of the exercising crew member while performing Medical Experiments M-19 and M-20. The nose clip functions in a positive, spring-actionlike manner, without producing undue discomfort.

3.4.2.2 Mouthpiece: The design of the mouthpiece contains the general features of a commercially available mouthpiece, Model No. P-357, manufactured by Warren E. Collins, Inc., 555 Huntington Avenue, Boston 15, Massachusetts.

The mouthpiece provides easy, yet gas-tight, mating with its interface.

3.4.2.3 Breathing Valve: The breathing valve incorporates the general features of a commercially available breathing valve, Model No. 188-00, manufactured by Sierra Engineering Company, Sierra Madre, California. The breathing valve provides easy, yet gas-tight, mating with its interfaces. The breathing valve is not to be used during the performance of Medical Experiment M-20.

3.4.2.4 Interconnecting Tubing: The interconnecting tubing is 32 inches in length and the outside diameter does not exceed 1.0 inch. To obtain maximum flexibility, the main body of the tubing is of corrugated design.

The interconnecting tubing is used only during the performance of Medical Experiment M-19.

The interconnecting tubing provides easy, yet gas-tight, mating with its interfaces.

3.5 Reliability

Reliability is a prime consideration in the design, development, fabrication, and operation of the pulmonary gas collection assembly and its components. The reliability goal for the pulmonary gas collection assembly and its associated hardware is at least 1000 hours mean time between failures (MTBF) under any combination of loads and environmental design requirements, specified in the Statement of Work.

3.6 Failure and Safety

The paramount importance of crew safety and space-flight mission success, require that special consideration be given to failure modes and safety in the design, development, fabrication, and operational phases of the complete pulmonary gas collection assembly program. The assembly and its associated hardware will not, under any combination of loads or requirements as specified in this Statement of Work, release any substance, debris, or contaminants endangering crew safety or mission success. The release of substance, debris, or contaminants that can conceivably occur will take place in a completely safe manner and will not propagate sequentially.

4. DESIGN AND DEVELOPMENT

The design and development program consisted of layout and design of the overall system arrangement, a design approval test program including materials selection, fabrication of mockups of all end items in both the storage configuration and the operational configuration, and the fabrication of initial prototype units.

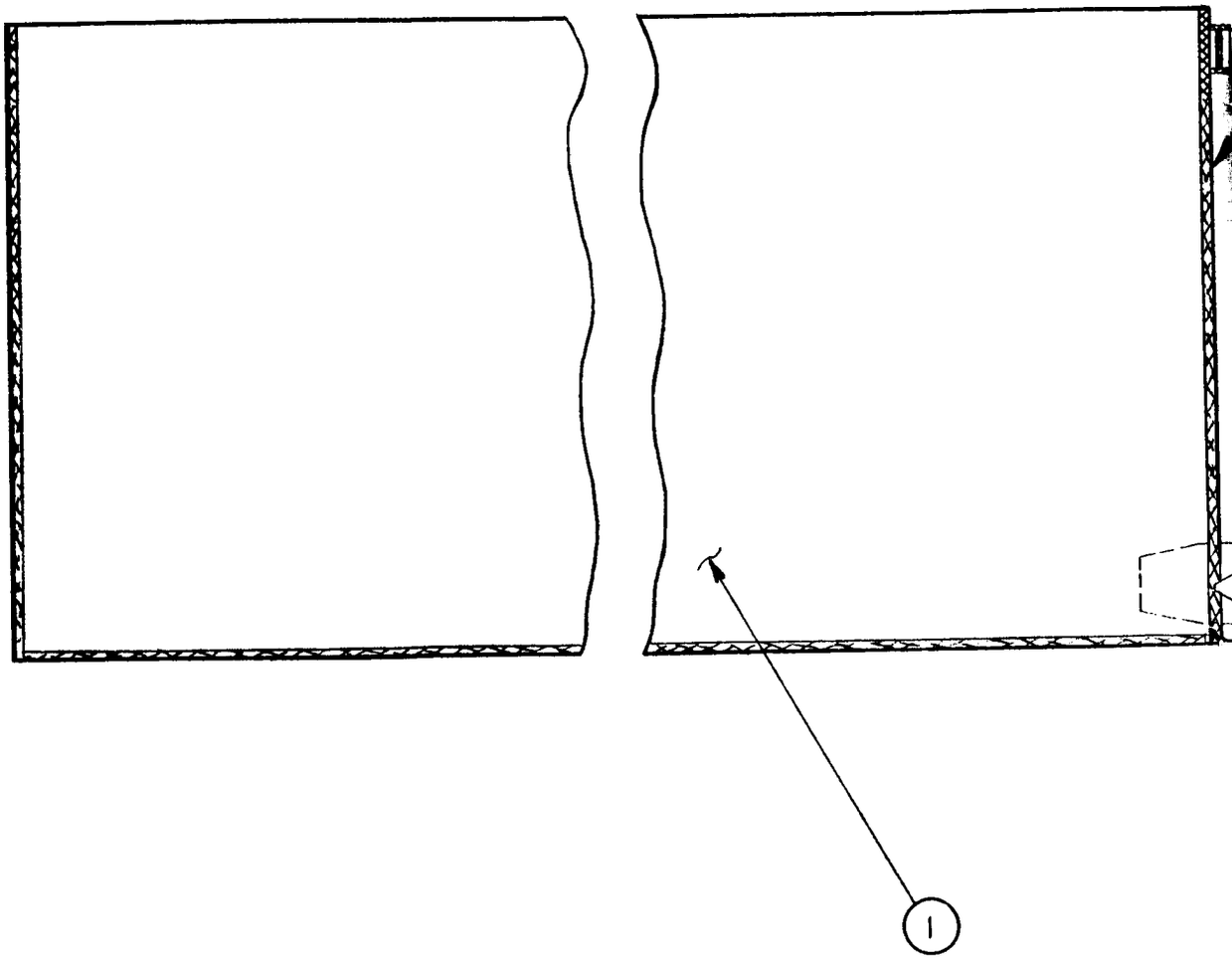
4.1 System Arrangement

The system arrangement is shown in figure 2, Pulmonary Gas Collection Assembly and Associated Equipment Flow Diagram. Storage configuration dimensions are also shown in figure 2. This flow diagram was made to illustrate the subsequent hookups required for mating the gas collection assembly and associated equipment with the onboard gas volume meter in order to perform Medical Experiments M-19 and M-20.

Extensive effort was expended on the valve channeling arrangement of the gas inlet and outlet pathways. Breadboard arrangements were assembled for evaluating the valve and channeling design. To improve the effectiveness of the valve channeling, a separate outlet port was added to allow unrestricted transfer of gas from the collection bag to the gas volume meter. This modification also permitted an improved flow arrangement through the inlet port and inspiratory valve either to the collection bag or to the crew compartment.

4.2 Gas Collection Assembly

(See figure 7):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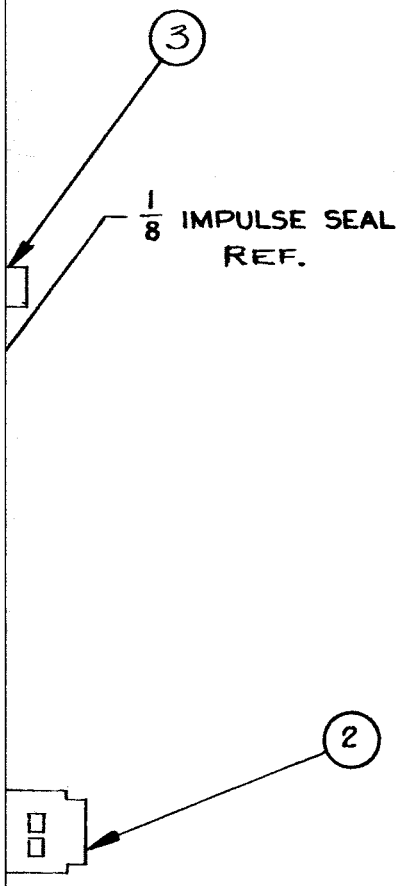


SYMBOLS:

1. ASSEMBLE PER MELPAR PROCESS SPEC. ES-1308

Figure 7. Pulmonary Gas Collection Assembly

4.2.1 Design

Two basic items had to be designed as components of the pulmonary gas collection bag: one was the main body, the bag itself; the other was the valve assembly which consisted of the gas inlet, the gas outlet, and valving and routing channels.

Main Body: The main body, the bag, was made in the form of a rectangular cylinder to contain a volume of 80 liters of expired air. Since this was a requirement of the main body, the dimensions in turn were fixed by the volume requirements. Further, the bag was designed to have optimum storability within the limits of the storage configuration, rectangluar in shape and not exceeding the dimensions $\frac{1}{2}$ by 3 by 5 inches. The main body was designed so that it could be operated a minimum of 14 cycles with a restorability operation between each cycle.

Valve Assembly: Several designs were considered for the valve assembly. The one ultimately chosen as optimum for this program was described in Melpar Process Specification ES 1308 delivered to NASA during performance of the program. This valve assembly design requires minimum effort on the part of the astronaut to control the channeling of expired air, either to the space cabinet or into the main body, and it meets all the operational requirements.

Overpackage: The overpackage was designed to contain, under vacuum, the main body and valve assembly of the pulmonary gas collection bag. Further, the overpackage was designed with a "cut-through flap" to facilitate removal of the collection bag from the package and to accommodate the refolded main body and valve assembly after the experiment has been completed.

4.2.2 Materials

Main Body: Two-mil polyethylene was chosen as the material of construction for the main body of the gas collection assembly. Several materials were evaluated, as reported in Melpar's report, "Test Data from Design Approval Testing," attached as appendix A; but the two-mil polyethylene met the optimum requirements of heat sealability, foldability within the confines of the storage volume, and durability for the repeated operational and storage cycles. In addition, the tensile strength, 900 psi, of the two-mil polyethylene was high enough to withstand adverse handling during operation, yet it was low enough to meet the requirements for bursting in the event of spacecraft decompression.

Valve Assembly: The valve assembly was constructed of polyethylene material ranging from 2 to 15 mils in thickness as described in detail in Melpar Process Specification ES 1308.

Overpackage: Several overpackage materials were considered and evaluated. The material selected for the overpackage is an improved Apollo plastic laminate material consisting of polyethylene, Aclar, and Mylar. The physical properties and permeability characteristics of this material are described in Melpar's Engineering Specification ES 1404 (supplied to NASA during performance of the program). Failures of this material were noted in preliminary testing, but subsequent developmental and qualification testing proved that the material was satisfactory for use in this program.

4.3 Associated Equipment

The associated equipment for use in this program consisted of nose clip, mouthpiece, breathing valve, and interconnecting equipment. An

extensive vendor survey was accomplished to find suitable suppliers of these items.

As a result of the survey, Melpar procured the mouthpieces (part number R357061) from the R. E. Darling Company in Gaithersburg, Maryland. A photograph of the mouthpiece is shown in figure 4. Figure 8 is Melpar's procurement drawing providing detailed design specifications of the procured mouthpiece.

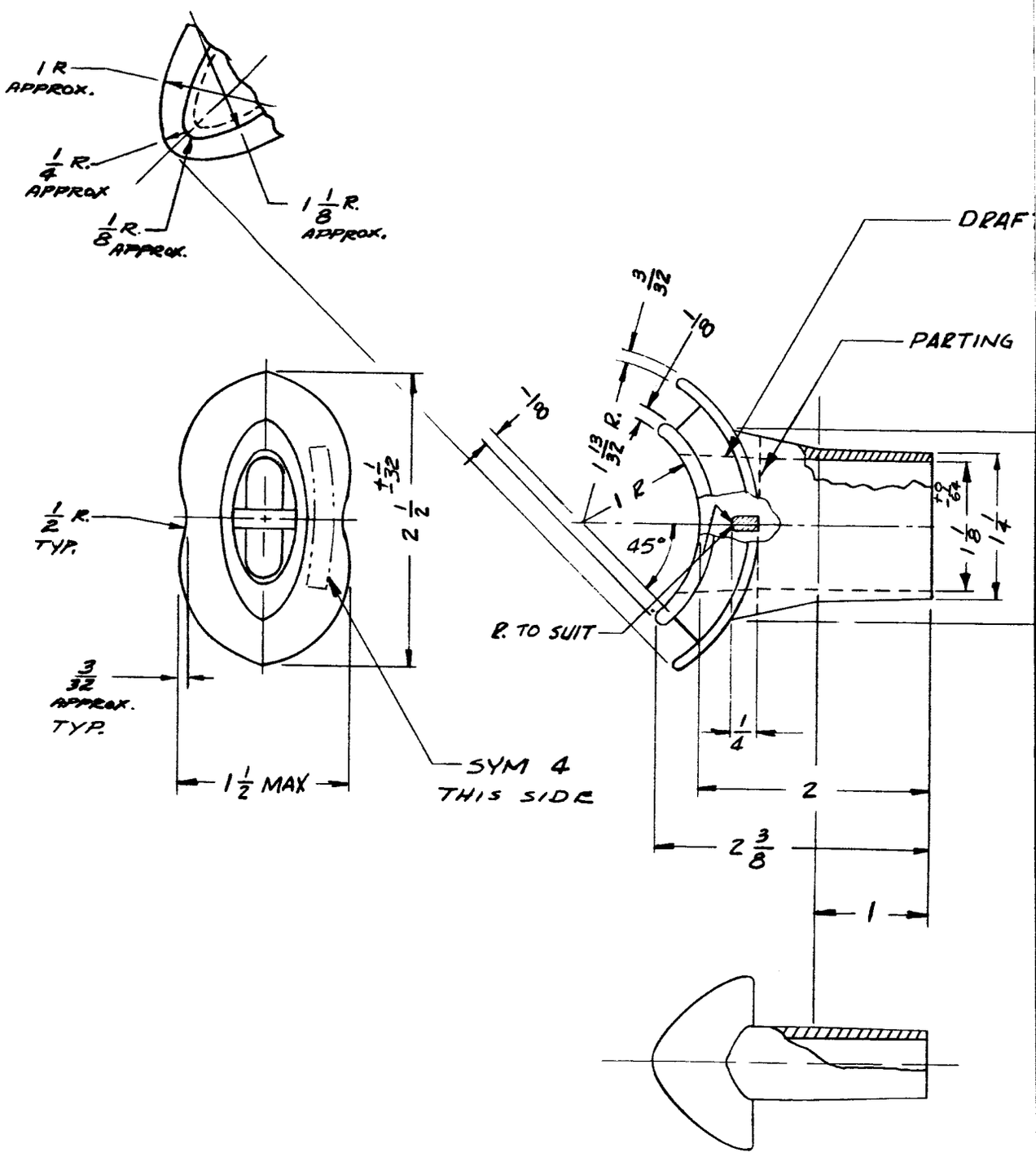
Melpar selected Sierra Engineering Company of Sierra Madre, California, to supply both the breathing valve (figure 5) and the interconnecting tubing (figure 6). Melpar's procurement drawings for the breathing valve (R357173) and the interconnecting hose (R357204) are shown in figures 9 and 10.

Two important design factors were considered in the selection of the nose clip. It must be an effective and reasonably comfortable device when in use by the astronaut and, in storage, it must fit inside a small space in the mouthpiece. In addition, the materials used in manufacture must be acceptable under the applicable specifications and environmental test. No commercially available nose clips were found meeting all of these requirements. Therefore, Melpar selected a nose clip assembly from W. J. Voit Rubber Company, stripped the rubber and zinc plating, then gold plated the nose clip blank and completed the assembly with General Electric potting compound RTV-60. See figure 4 for the completed assembly.

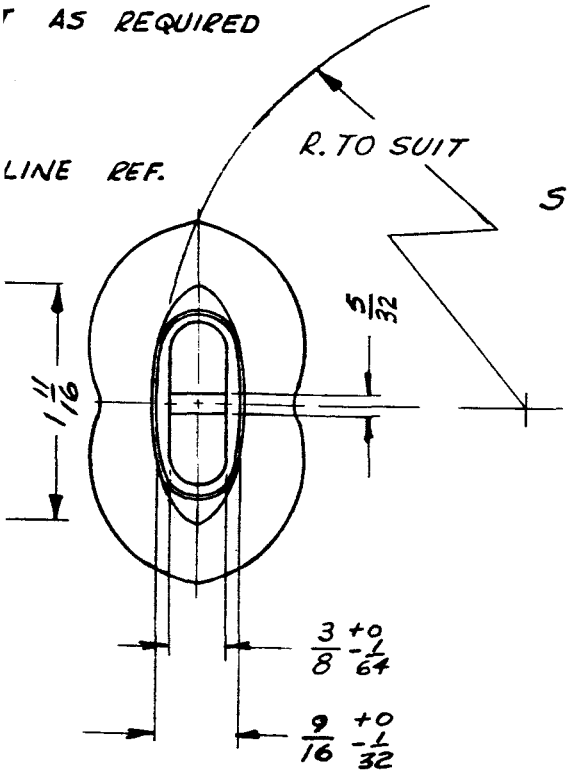
4.4 In-Flight Operation Instructions

To provide a full understanding of the equipment and its use, in-flight operational procedures are given below. These procedures may be repeated as many as 14 times during a single mission. (See figure 2.)

R357061


1 R APPROX.
1/4 R. APPROX
1/8 R. APPROX.
1 1/8 R. APPROX.
DRAF
PARTING
3/32
1/8
1 13/32 R.
1 R
45°
1/10
+1/32
2 1/2
1/2 R. TYP.
3/32 APPROX. TYP.
1 1/2 MAX
SYM 4 THIS SIDE
R. TO SUIT
1/4
2
2 3/8
1

28-1



SYMBOLS:

1. SOURCE
   R. E. DARLING CO. INC.
   16021 INDUSTRIAL DR., P.O. BOX 666
   GAITHERSBURG, MD.
   CODE IDENT NO. 83452

2. MATERIAL - SILICONE COMPOUND - SILASTIC 651, AMS 3335, MIL-R-5847 CLASS 1A GRADE 50

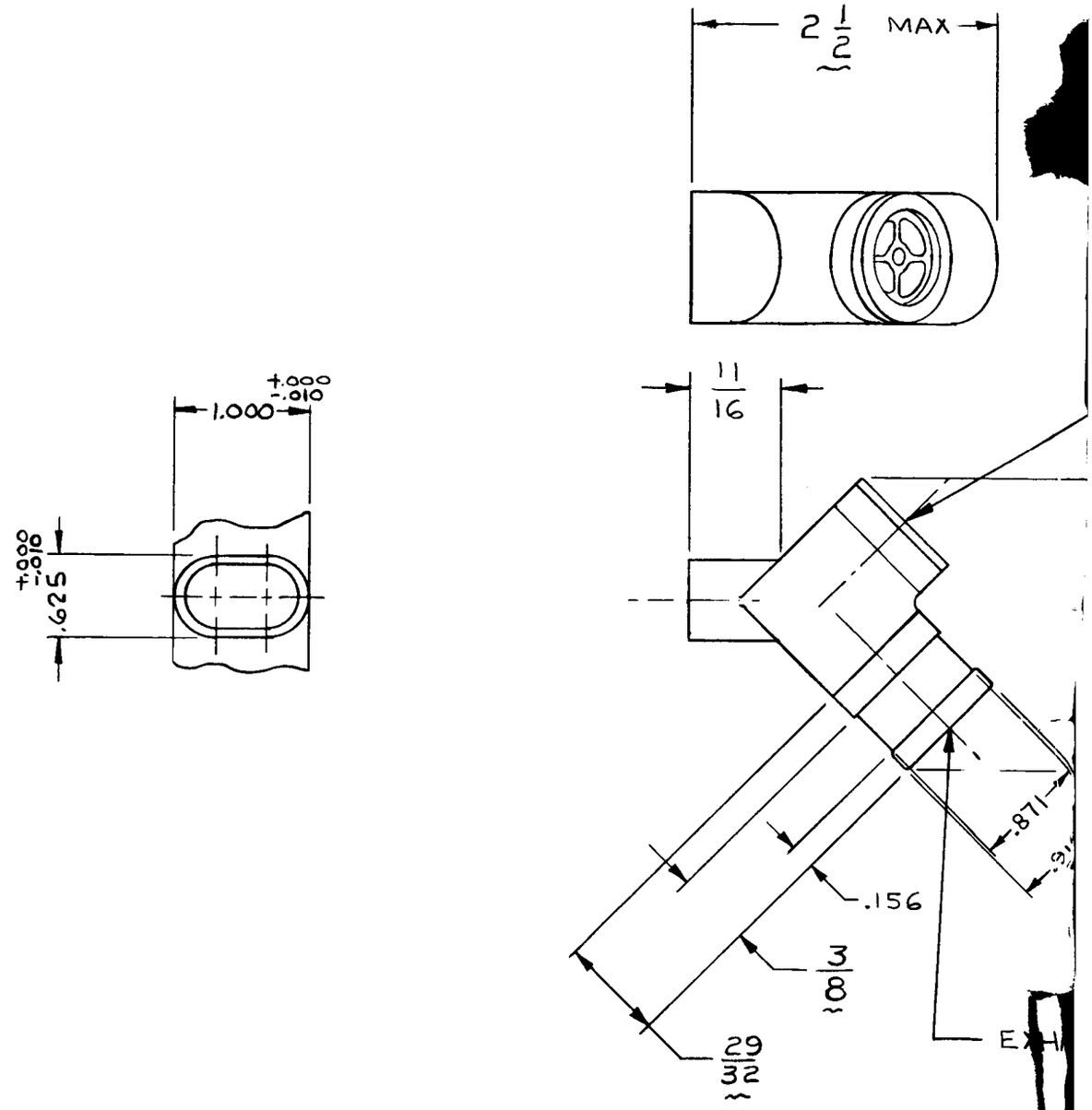
3. APPLICABLE DOCUMENTS:

   MIL-STD. 130 IDENTIFICATION MARKING
   NASA-NPC-200-3 INSPECTION SYSTEM PROVISIONS
   NASA-NPC-200-2 QUALITY PROGRAM PROVISIONS
   MC 999-0058 MATERIALS SPECIFICATIONS

4. APPLY VENDOR PART AND CODE IDENT NO IN ACCORDANCE WITH MIL-STD-130-B IN THE AREA SHOWN

Figure 8. Mouthpiece

R357173



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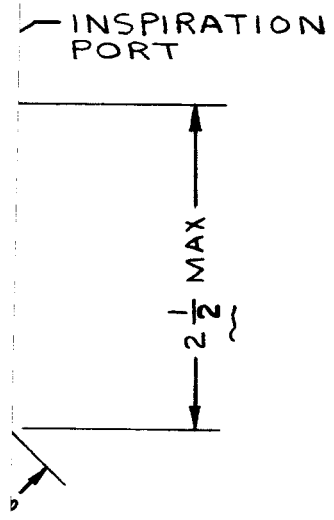


SYMBOLS:

1. VENDOR:

   SIERRA ENGINEERING CO.
   SIERRA MADRE, CALIFORNIA
   CODE IDENT NO. 92114
   SIERRA PART # 188-101

2. DESIGN SPECIFICATIONS:

   A. FLOW CHARACTERISTICS:

FLOW/LPM	30	60
ΔP/IN. H_2O	.90	1.40

   B. INTERNAL "DEAD AIR" SPACE: APPROX 15CC

   C. ALL MATERIALS TO BE APPROVED PER NAA/S AND ID SPECIFICATION NUMBER MC999-0058

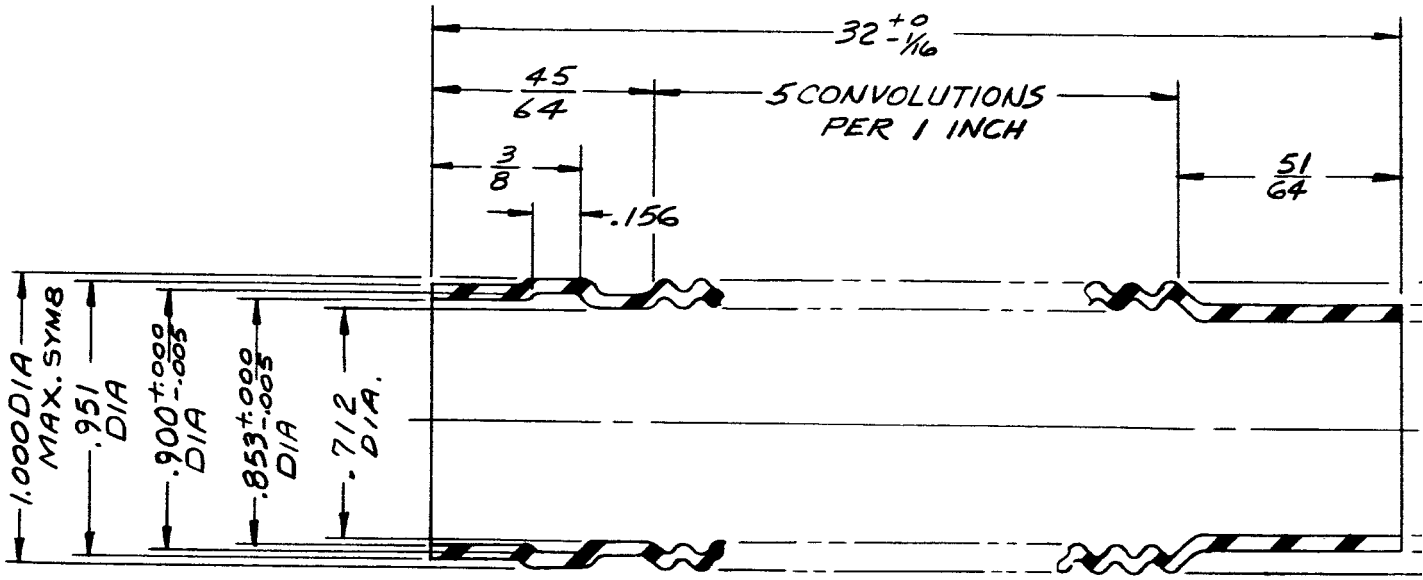
3. APPLICABLE DOCUMENTS:
   MIL-STD-130 IDENTIFICATION MARKING
   NASA-NPC-200-3 INSPECTION SYSTEM PROVISIONS
   NASA-NPC-200-2 QUALITY PROGRAM PROVISIONS
   MC 999-0058 MATERIALS SPECIFICATIONS

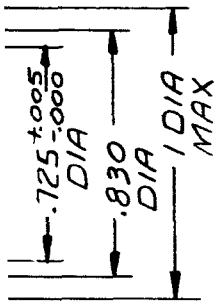
4. VALVES SHALL BE TESTED TO INSURE THAT THE INSPIRATION PORT AND EXPIRATION PORT VALVE DIAPHRAGMS ARE FUNCTIONING.

ALATION TUBE CONN

Figure 9. Valve, Breathing

R357204


32 +0 -1/16
45/64
5 CONVOLUTIONS PER 1 INCH
3/8
.156
51/64
1.000 DIA MAX. SYMB
.951 DIA
.900 +.000 -.005 DIA
.853 +.000 -.005 DIA
.712 DIA.



SYMBOLS:

1. MATERIAL: SILICONE COMPOUND
   SILASTIC 651, AMS 3335
   MIL-R-5847 CLASS 1A GRADE 50
   OR EQUIV. APPROVED COMPOUND

2. APPLICABLE DOCUMENTS:
   MIL-STD-130 IDENTIFICATION MARKING
   NASA-NPC-200-3 INSPECTION SYSTEM PROVISIONS
   NASA-NPC-200-2 QUALITY PROGRAM PROVISIONS
   MC 999-0058 MATERIALS SPECIFICATIONS

3. VENDOR:
   SIERRA ENGINEERING CO.
   SIERRA MADRE, CALIF.
   CODE IDENT NO. 92114

4. THE HOSE SHALL BE ABLE TO WITHSTAND A MINIMUM 3" BEND RADIUS (RADIUS TO CENTERLINE OF HOSE) AND STILL MAINTAIN ITS NORMAL INTERNAL CONFIGURATION.

5. MINIMUM WALL THICKNESS THRU CONVOLUTIONS TO BE .040.

6. LEAK TEST UNDER WATER AT 2 PSI -NO LEAKAGE ALLOWED.

7. THE MAXIMUM DIMENSIONS FOR THE HOSE STORAGE CONFIGURATION AREA ARE : 1 X 7 X 6.82 INCHES.

8. THIN FLASHING AT THE MOLD PARTING LINE MAY EXTEND UP TO 1/16 INCH BEYOND THE O.D. OF THE TUBING.

Figure 10. Hose, Interconnecting

4.4.1 Medical Experiment No. M-20 (See figure 11)

The crewmember's procedure for carrying out Medical Experiment No. M-20 is as follows:

a. Remove the gas collection assembly, the mouthpiece, and the nose clip from their storage configurations.

b. Attach the mouthpiece to the gas inlet of the gas collection assembly and determine by inspection that the outlet clamp is closed. If not firmly closed, squeeze the polyethylene clamp between the thumb and forefinger along its entire length. (With the mouthpiece in place, with the nose clip properly positioned on the crewmember, and with the gas inlet clamp closed, the routing of the respiratory gases is such that cabin air is inhaled and the expired gases are returned to the crew compartment through the valving and channeling arrangements of the gas collection assembly.)

c. At a specified point in time, open the gas inlet clamp by grasping the tabs on each side of the clamp and gently pulling outward. With the clamp in the open position, crew compartment air is inhaled through the inspiratory valve of the assembly, and expired air is channeled to and collected within the main body of the assembly.

d. At the termination of the specified collection period, close the gas inlet clamp to seal the expiratory gases within the assembly. At this point remove the mouthpiece and nose clip and mate the gas outlet of the assembly with the inlet port of the gas volume meter. (Reference is made to Medical Experiment No. M-19). The insertion of the gas outlet over the inlet port of the gas volume meter serves to open the outlet clamp so

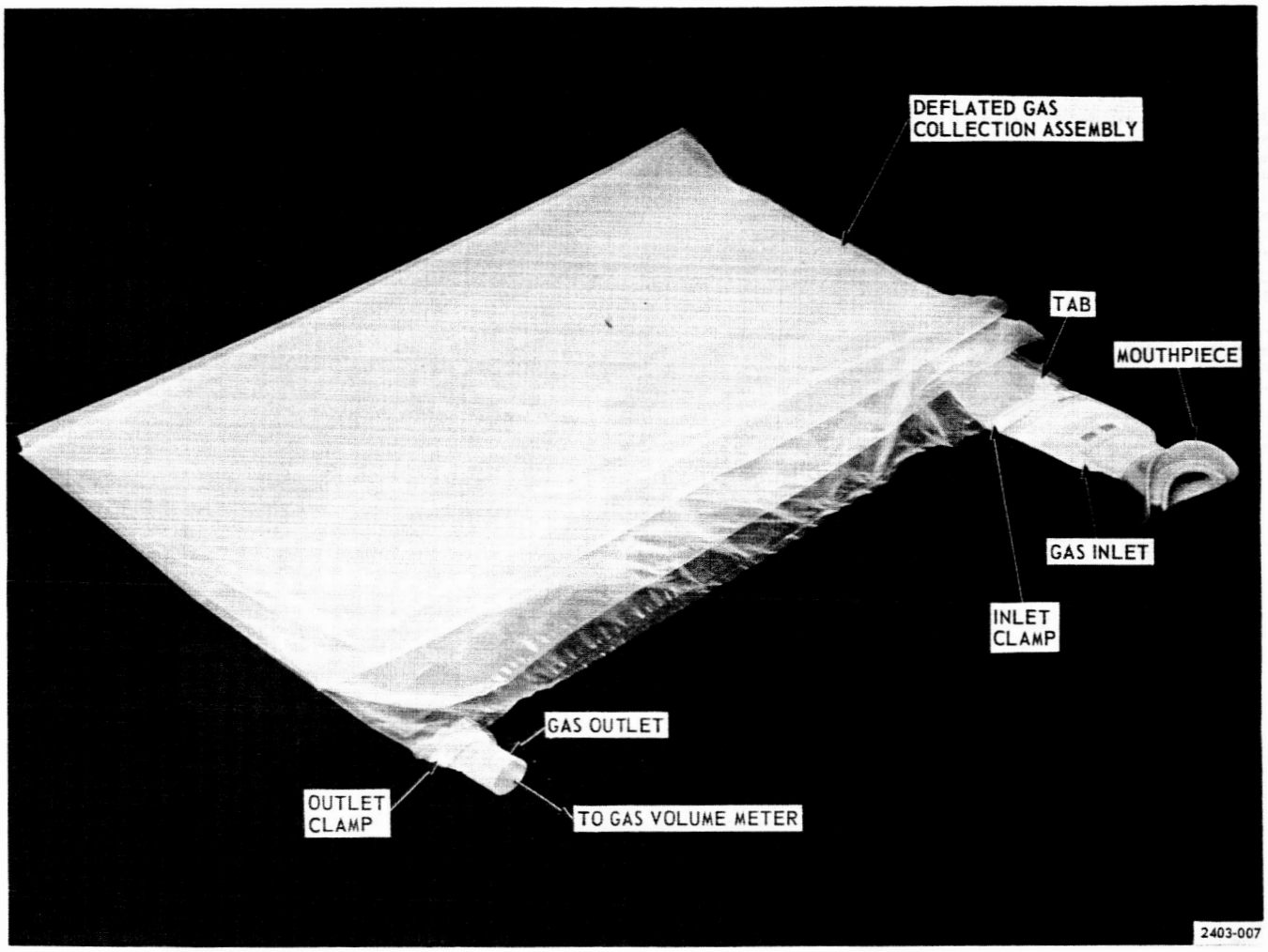


Figure 11. Equipment Configuration for Medical Experiment No. M-20

that the collected gases may be transferred to the meter. To effect the transfer to the meter, gently and slowly compress or collapse the collection assembly. The meter provides a direct reading measurement of the volume of the collected expiratory gases.

e. Disconnect the gas collection assembly from both the gas volume meter and the mouthpiece. Recompact the assembly and stow all of the equipment until required for a subsequent measurement.

4.4.2 Medical Experiment No. M-19 (See figure 12)

The crewmember's procedure for carrying out Medical Experiment No. M-19 is contained in the following paragraphs:

a. Remove the interconnecting tubing and the breathing valve assembly from their storage configurations.

b. Attach the mouthpiece to the mating connection of the breathing valve (figures 4 and 5). Also, connect one end of the interconnecting tubing to the exhalation connection of the breathing valve and the other end to the gas volume meter inlet port connection. With the mouthpiece in place and the nose clip properly positioned on the crewmember, the routing of respiratory gases is such that cabin air is inhaled through the inspiration port and expired gases are channeled through the breathing valve and interconnecting tubing directly into the gas volume meter.

c. Remove the nose clip. Disconnect the mouthpiece from the breathing valve, the breathing valve from the interconnecting tubing, and the interconnecting tubing from the gas volume meter.

d. Return all of the equipment to their respective storage configurations until required for a subsequent measurement.

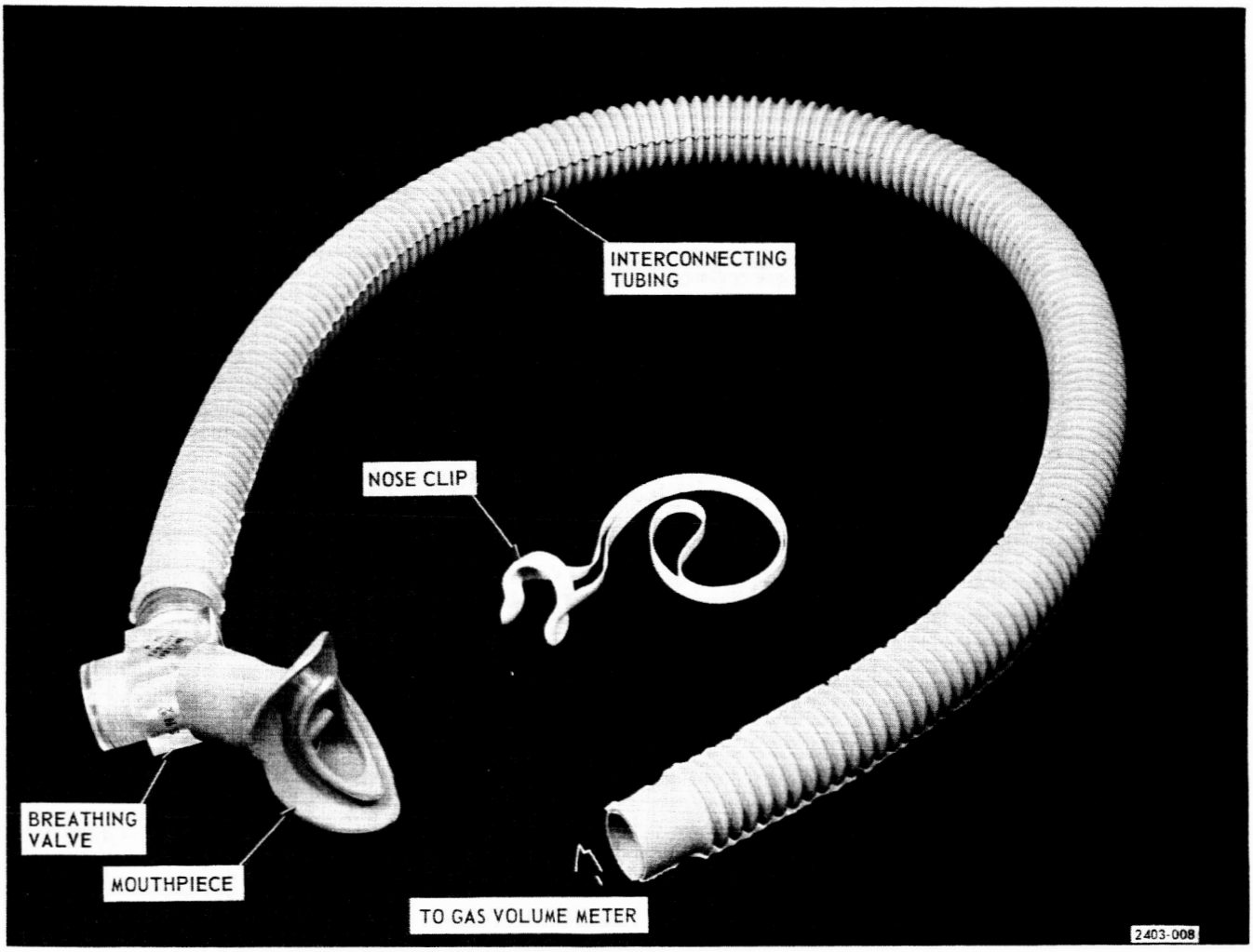


Figure 12. Equipment Configuration for Medical Experiment No. M-19

5. QUALIFICATION TESTING

The qualification testing program consisted of preparation and approval of qualification test plans and procedures and the performance of tests on the first production units. These tests were conducted to verify the inherent capability of the design to meet the performance and environmental requirements specified in the contract statement of work and summarized herein.

Qualification tests were performed on two production units of the gas collection assembly, the nose clip and the mouthpiece, and on one production breathing valve and interconnecting tube. These units were fabricated using the same materials and tooling processes and under exactly the same conditions as those intended for quantity production.

Each unit, subjected to qualification tests, was examined to determine compliance with the requirements of the contract. These requirements included size, weight, workmanship, tests which demonstrate functional requirements, and output characteristics.

Appendix "B" summarizes the test procedures and results for the Pulmonary Gas Collection Assembly and Associated Equipment items subjected to these qualification tests.

6. PRODUCTION

6.1 General

The production phase of the Gas Collection Assembly program included preparation of process specifications to facilitate the fabrication of the gas collection assembly, manufacture and/or procurement of qualification test items and deliverable end items given below, and acceptance testing of the deliverable items prior to shipment.

The gas collection assemblies were manufactured in Melpar's Materials Laboratory in order to utilize techniques previously developed on other contracts.

The mouthpieces were procured from the R.E. Darling Company. Sierra Engineering supplied both the breathing valve and the interconnecting hose.

A commercial nose clip was procured from W.J. Voit Rubber Co. and modified to meet the requirements of this program.

Prior to delivery each unit was examined to determine compliance with Melpar Acceptance Test Procedures B202.03 and B202.02, delivered to NASA during the performance of the program.

6.2 Fabrication Techniques

Fabrication techniques of the main body, valve assembly, and overpackage are described in detail in the Melpar Process Specification ES 1308. (This specification was delivered to NASA-MSC during the performance of the program.) Impulse heat-sealing techniques were used for the fabrication of all the components and the overpackage. The vacuum evacuation of the overpackage with the main body and valve assembly components and the

final sealing of the overpackage were accomplished in Melpar's vacuum heat-sealing apparatus. Melpar's vacuum heat-sealing apparatus is identical to that used in vacuum sealing Apollo space-food packages. In all cases, a vacuum of less than 10 millimeters of pressure was achieved before the heat-sealing function was performed.

6.3 Production Equipment Delivered

The following are hardware items manufactured and delivered under this phase of the program:

Description	Quantity		
	Qualification Test Units	Operations & Training Units	Flight and Backing Units
Pulmonary Gas Collection Assemblie	2 ea	36	12
Nose Clip	2 ea	12	6
Mouthpiece	2 ea	12	6
Breathing Valve	1 ea	2	3
Interconnecting tubing	1 ea	2	3

APPENDIX A

TEST DATA FROM DESIGN APPROVAL TESTING FOR NASA MANNED SPACECRAFT CENTER

Date 16 June 1966

TEST DATA

from

DESIGN APPROVAL TESTING

for

NASA MANNED SPACECRAFT CENTER

Houston, Texas

per

NASA Contract No. NAS 9-5514

Melpar Job 5768

Prepared by:

O. E. Seastrom
Sr. Engineer

Approved by:

E. Parrish
Test Supervisor

Reviewed by:

R. Chouinard
Sr. Test Engineer

P. J. McCabe
Project Engineer

DESIGN APPROVAL TESTING

TEST PROCEDURE NUMBER:

B202.00 (Storage Configuration)

B202.05 (Operational Configuration)

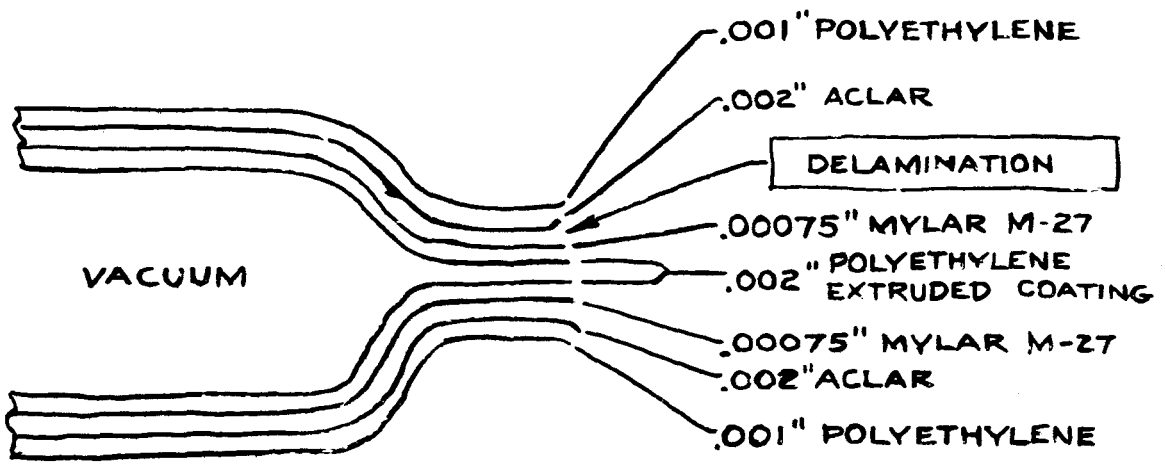
PROTOTYPE TEST ITEMS:

Name (End Items)	Part No. (Melpar)	Serial No.
Pulmonary Gas Collection Assembly	R 357439	1
Mouthpiece	R 357061	1
Noseclip (Stored inside mouthpiece)	R 257430	
Breathing Valve	R 357173	2
Interconnecting Tubing	R 357204	1

Preliminary Testing

Prior to the start of the Design Approval Tests certain preliminary tests were conducted at Melpar's Test and Evaluation Laboratory. These initial tests indicated a tendency for the laminated material used for packaging the end items to partially delaminate under temperature-decompression conditions.

Although delamination of the overwrap material was noted, the packages had retained their vacuum. The sketch below illustrates how it is possible to get delamination of this material and still maintain a vacuum within the package.



CROSS SECTION VIEW

Since the delamination occurred at the Aclar-Mylar interface there still remained a protective laminate of Mylar M-27 and polyethylene. However, it is desirable that this condition be eliminated or held to a minimum.

In view of the above mentioned condition, sealing techniques were reviewed and it was determined that complete fusing of the laminated material at the outer edge of the seal was desirable. The prototype units were packaged accordingly and sealed in this manner.

Back-Up Testing

Since it is desirable to have other materials evaluated for possible use on packaging the collection assembly bag and associated equipment; two other materials were selected and included along with the prototype units throughout the design approval tests.

The two materials selected for test were as follows:

1. Aclar 33 c Fluorohalocarbon film. This is a flexible thermoplastic film made from fluorinated-chlorinated resins.

2. Aluminum Foil Laminate - This material is marked "Continental" and is referred to as EXP-9575-1. It is obtained from Continental Can Company, Flexible Packaging Division and is made up as follows:

.002	in.	Polyethylene
50	ga.	Mylar
.00035	in.	Aluminum Foil
.001	in.	Polyethylene

The Aclar material failed during the high temperature test but the Aluminum Foil material successfully went through all the tests and close inspection after testing revealed no visible signs of damage or any apparent delamination of material.

Prototype Testing

One of each of the above listed prototype end items unless otherwise noted were submitted to the following Design Approval tests:

1. High Temperature Test (Initial Storage Configuration) Reference - T.P. B202.00 Para. 5.1.1.

Test environment and requirements:-

Test Period	:	48 hours
Atmosphere	:	Pure Oxygen
Pressure	:	5 ± 0.5 PSIA
Relative Humidity	:	15% or less
Temperature	:	$71 \pm 2^{o}C$ ($160 \pm 3.6^{o}F$)

Objective

During the above test no crushing, distortion opening of seals or other damage deleterious to the proper operation of the test items shall occur.

Procedure

The internal walls of the test chamber were lined with brown paper to provide an emissivity of .8 or greater. The test items were placed on a black metal fixture and enclosed by a glass bell jar which was sealed to an aluminum plate. The chamber temperature was monitored with two thermocouples taped to the outer periphery of the bell jar. The internal ambient temperature of the bell jar was monitored by a third thermocouple passed through a sealed port in the aluminum plate and placed between the black metal fixture and the internal side of the bell jar. The oxygen atmosphere was maintained by providing a steady flow of oxygen to the bell jar through a copper tubing sealed to a port on the aluminum fixture and continuously pumping the bell jar with a vacuum pump. The proper pressure (5 psia) was maintained by adjusting a valve on the tubing interconnecting the vacuum pump and bell jar. The pressure was monitored on a mercury manometer and the column height determined by subtracting 10.2 inches of mercury (5 psia) from the corrected absolute barometric pressure. The results were converted to psia.

Results - A visual examination of the test items performed upon termination of the test revealed no apparent defect.

2. Low Temperature Test (Initial Storage Configuration)

Reference - T.P. 202.00 Para. 5.1.2

Date of Test - 12 May 1966

Test Requirements - 4 hours minimum at a temperature of

$-17.8 \pm 2^{o}C$ ($0 \pm 3.6^{o}F$)

Objective:

There shall be no crushing, distortion, opening of seals or other damage deleterious to the proper operation, life and serviceability of the equipment as a result of this test.

Procedure

The internal walls of the test chamber were lined with brown paper to provide an emissivity of 0.8 or greater. The test items were placed on a black metal fixture and the chamber temperature reduced to $0^{o}F$. $\pm 3.6^{o}F$. This condition was maintained for four hours and the test chamber returned to room temperature.

Results

A visual examination performed upon termination of the test revealed no apparent defects to the test items.

3. High Temperature Decompression Test

(Initial Storage Configuration)

Reference - T.P. 202.00 Para. 5.1.1.1

Date of Test - 12 May 1966

Test Requirements - -

Test Time	:	1.5 hours
Pressure	:	1×10^{-6} psia
Relative humidity	:	15% or less
Temperature	:	$71 \pm 2^{o}C$ ($160 \pm 3.6^{o}F$)

Objective

There shall be no crushing, distortion, opening of seals or other damage deleterious to the proper operation, life and serviceability of the equipment as a result of this test.

Procedure

The test items were placed in an aluminum tray fastened to an aluminum fixture containing the heating element and cooling copper tubing. The heaters were electrically connected to connectors on the vacuum chamber. The cooling coils were connected to a liquid nitrogen tank by copper tubing through a sealed port on the vacuum chamber. The temperature was controlled ($160^{o}F \pm 3.6^{o}F.$) by a balanced bridge of a differential temperature recorder. One leg of the bridge was connected to a variable resistive

element (resistance proportional to temperature) fastened to the fixture containing the heating elements and cooling coils inside the chamber. The other leg of the balanced bridge was connected to a variable resistance box outside the chamber with a programmed resistance equal in value to that of the resistive element in the chamber at + 160°F. Any unbalanced current developed in the bridge as a result of temperature below or above 160°F. was amplified by a D.C. amplifier and operated a relay. The relay operation activated a solenoid to allow liquid nitrogen to flow through the cooling coils when the temperature tended to go above + 160°F. The test items were subjected to High Temperature Decompression for one and one half hours at 160°F. $\pm$ 3.6°F. and 5.2×10^{-5} mm Hg or lower.

Results

A visual examination upon termination of the test revealed no apparent defects to the test items.

4. Temperature-Pressure (Initial Storage Configuration)

Reference - T.P. 202.00 Para. 5.1.3

Date of Test - 13 May 1966 to 14 May 1966

Test Requirements --

Pressure - reduced to 1×10^{-6} psia

With chamber temperature at 160°F., lower to 0°F in 45 minutes and raise to 160°F. in 45 minutes to constitute one cycle. At the completion of 15 additional cycles the pressure and temperature shall be returned to room ambient temperature.

Upon conclusion of test, remove the units from the chamber. For satisfactory results there shall be no crushing, distortion, opening of seals or other damage deleterious to the proper operation, life and sevice-ability of the equipment.

Procedure

The test items were subjected to 16 cycles of temperature pressure testing utilizing the same procedure mentioned in paragraph 3 of this report. In addition, a liquid nitrogen tank was connected to coils wound around a shroud inside the vacuum chamber to provide the 0°F. temperature required during cycling. A variable resistance box and a forty five minute timer were used in addition to the controlling equipment mentioned above. One resistance box was programmed to balance the bridge at 0°F. while the other was programmed to balance the bridge at $\pm$ 160°F. The timer was used to switch from one variable resistance box to the other at the end of each forty five minute intervals. This arrangement allowed the temperatures to be varied from 160°F. to 0°F. and back to 160°F. ($\pm$ 3.6°F.) in one and a half hours. The test items were subjected to sixteen such cycles at a pressure of 5.2×10^{-5} mm Hg or lower.

Upon completion of the test a visual examination of the test items revealed no apparent defects.

5. Subsequent Storage Configuration Decompression Test, (Test performed on gas collection assembly only)

Reference - T.P. 202.00 Para. 5.1.4

Date of Test - 16 May 1966

Test Requirements --

Test Period	:	17 minutes
Pressure	:	$5.2. \times 10^{-6}$ mm Hg or less
Relative Humidity	:	15% or less
Temperature	:	$71^{o} \pm 2^{o}C$ ($160^{o} \pm 3.6^{o}F.$)

The maximum volume of the test item shall not exceed 30 cubic inches during exposure.

The gas collection assembly was removed from its initial storage configuration, unfolded, and the functional operation simulated by using a bellows to inflate the unit. The unit was then deflated, pressed flat, recompacted, and replaced in the subsequent storage configuration. The package was then placed in the vacuum chamber and the procedure of paragraph 3 applied. In addition, a scale graduated in one eighth inches was placed directly behind the package to measure the height of the test unit during exposure.

Results

A visual examination performed from outside the chamber during the entire test revealed that the volume remained at approximately 20 cubic inches.

Upon the termination of this test a visual examination revealed no apparent damage to the test item.

6. Endurance Test (Operational Configuration) Test item Gas Collection Assembly only.

Reference - T.P. 202.05 Para. 5.1.4

Date of Test - 16 May 1966 to 19 May 1966

Test Requirements -

Inflate the assembly to 1 atmosphere pressure and place in the test chamber and maintain the environment for 48 hours.

pressure	:	local atmosphere
temperature	:	160°F.

On conclusion of test remove the assembly and carefully examine for any defect or damage.

Procedure

The Gas Collection Assembly was subjected to a temperature of 160°F. $\pm$ 3.6°F. for forty eight hours under operational conditions. The

test items was deflated and re-inflated in approximately ten minutes and held inflated for five minutes to constitute one cycle. The test unit was subjected to at least 192 such cycles during the forty eight hour period. During the deflating period the air supply was shut off for three minutes by releasing the intake solenoid and activating an exhaust solenoid placed in the path of a copper tubing interconnecting the exhaust port of the test unit to a vacuum pump.

Since these are Design Approval tests and are intended mainly to create confidence in the design, some leeway was taken in implementing this test. An existing facility was used which included a timing mechanism set to provide inflation and deflation within a 15 minute cycle. This did expedite the testing but imposed excessive cycling on the test item resulting in a far more stringent test than required.

It was also found that the air currents set up by the circulating fan' created a severe buffeting of the collection assembly bag especially during inflation and deflation. This buffeting resulted in repeated strain being placed on certain points due to the repetitive flexing pattern during each cycle.

The results of this test revealed no visible damage to the gas collection assembly; however, the points of continual flexing did prove to be damaged

as the subsequent leakage test (para. 12) indicates. Due to the findings from this test the set-up for the Qualification Endurance test will be reviewed and modified as required to prevent unwarranted environments from adversely effecting the test item. This completed the environmental testing portion.

7. Humidity Test

Reference - T.P. B202.05 Para. 5.1.3

Instead of performing the Humidity Test, the following documentation of previous humidity testing of 6061 T6 aluminum is submitted.

Job Name	-	Gas Chromatograph
Job Number	-	Contract NAS 9-2518 Melpar #4267.00800
Test Report	-	#2633
Test Item	-	Analyzer Chassis Rail Assembly, Melpar Part No. R535043

This test item which contained several 6061 T6 aluminum parts successfully completed the Humidity Tests in accordance with Mil - E - 5272 Procedure I.

8. Folding Resistance

Reference - T.P. B202.05 Para. 5.1.5

Date of Test - 25 April 1966

Test Requirement - This test was designed to evaluate the folding endurance of sheet or film materials by subjecting them to simultaneous twisting and flexing motion.

On concluding test, carefully examine the sample for defects, tears or damage of any sort.

Procedure

In operation, a 4 x 8 inch sample was clamped around two circular end plates, 4 inches in diameter (sample selected included a sealed seam). The lower plate was stationary, while the upper plate was rotated through 90° by a revolving crank and elevated by a roller-cam. This action was employed at a rate of 9 cycles per minute. The sample was removed after a predetermined number of cycles and examined for evidence of failure. Sample failure was defined as the presence of bubbles in water on one side of the sample as a gas pressure of 1 psi was applied to the other side. The measure of endurance was the number of cycles to failures.

Results

Upon conclusion of the folding resistance test, it was determined that 2 mil polyethylene tested approximately 100% better than three other materials previously tested at room temperature. The samples of polyethylene containing seams in them tested to be approximately 75% better than the three previously tested, and approximately 17% below unseamed polyethylene. The following tables show the maximum twist-flex cycling of the 2 mil polyethylene samples and the three previously comparative materials.

Material	Thick-ness	Sample No.	No. Cycles	Condition	Average Maximum Cycling	Machine Direction	Condition of Material
Polyethylene	2 Mil	1	100	Good	150		No seams
"	"	2	200	Bad		Parallel	
"	"	3	150	Good			
"	"	4	150	Good			
"	"	5	150	Good			
Polyethylene	2 Mil	6	150	Good	150		No seams
"	"	7	150	Good		Transverse	
"	"	8	150	Good			
Polyethylene	2 Mil	9	150	Bad	125		Seamed
"	"	10	125	Good		Parallel	
"	"	11	125	Good			
"	"	12	125	Good			
Polyethylene	2 Mil	13	150	Bad	125		Seamed
"	"	14	125	Good		Transverse	
"	"	15	125	Good			
"	"	16	125	Good			
			Comparative Materials				
Mylar "A"	2 Mil				70		No seams
Goodyear YMF 414	2 Mil				80		No seams
Goodyear YFR 338	2 Mil				50		No seams

All materials were tested at room temperature and parallel to and transverse to the machine direction. The machine direction being the direction the material was pulled from the rollers while being manufactured.

9. Tear Resistance

Reference - T.P. B202.05 Para. 5.1.6

Date of Test - 26 April 1966

Test Requirements - Check the tear resistance of .002 thick low density polyethylene material used on the Gas Collection Assembly.

Procedure

The test was run in accordance with ASTM D 1004, Tear Resistance of Plastic Film and Sheeting.

Specimens were punched with the die which is described in this method and tested on a model TTC Instron Universal Testing Machine. The Instron is a constant rate of elongation type machine with an accuracy of better than 1 percent of scale reading.

Rate of travel of the power actuating grip was a constant 20 in. per minute.

Initial grip separation was 1 inch on a set of pneumatically operated grips. Pneumatic grips minimize slippage by keeping a constant pressure on the sample even when necking in the grip area occurs.

Test Results --

Material	Sample No.	(lbs.) Tear Ultimate	Average
Polyethylene 2 Mil Parallel to MD	1	1.17	
	2	.97	
	3	.89	
	4	.91	
	5	.91	
	6	1.11	
	7	.96	
	8	.96	Average = 0.983
	9	1.08	
	10	.97	
Polyethylene 2 Mil Transverse to MD	1	1.39	
	2	1.25	
	3	1.36	
	4	1.24	Average = 1.29
	5	1.33	
	6	1.38	
	7	1.09	
	8	1.24	
	9	1.23	
	10	1.28	

10. Burst Strength

Reference - T.P. B202.05 Para 5.1.7

Date of Test - 26 April 1966

Test Requirements - To check the burst strength of three (3) sample sets of .002 thick low density polyethylene material. One (1) sample set to contain a sealed seam through the center parallel to machine direction and one (1) sample set perpendicular to machine direction.

Procedure

The apparatus used to determine the burst strength of the plastic film is of a design similar to that used to determine the burst strength of paper as described in ASTM D 774. The apparatus consists essentially of a pressure chamber with a flanged opening over which a specimen may be clamped, and a gauge for reading the internal pressure. The test, however, was modified to use air pressure in the chamber and the circular opening at the top to be 1.128 inches in diameter to yield a 1 square inch sample area.

Pressure was introduced into the chamber at a constant rate and the pressure required to rupture the specimen recorded.

Results --

Material	Sample No.	Burst PSI	Average	Comments
Polyethylene 2 Mil No seal	1	9.6	9.92	All breaks or splits due to bursting, split parallel to the M.D. of the material
	2	9.3		
	3	9.6		
	4	9.5		
	5	10.1		
	6	10.2		
	7	10.8		
	8	10.6		
	9	9.7		
	10	9.8		
Polyethylene 2 Mil Seal parallel to M.D.	1	11.4	11.05	
	2	9.8		
	3	12.3		
	4	9.6		
	5	11.6		
	6	11.0		
	7	11.0		
	8	11.6		
	9	11.3		
	10	10.9		
Polyethylene 2 Mil Seal transverse to M.D.	1	12.0	11.54	
	2	11.0		
	3	11.6		
	4	11.7		
	5	11.9		
	6	11.1		
	7	11.3		
	8	12.0		
	9	11.7		
	10	11.1		

11. Pressure Drop Test

Reference - T.P. B202.05 Para. 5.1.8

Date of Test - 27 May 1966

Test Requirement - check the pressure drop across the inspiratory valve. The pressure drop across the inspiratory valve shall not exceed one inch of water pressure.

The .1 inch water pressure drop test mentioned in T.P. B202.05 Para 5.1.8 (a) is not applicable since the revised design of the valving and channeling arrangement places the expiratory gas valve within the collection assembly bag. In view of this there is no pressure differential to measure between the expiratory valve and the inside of the bag or between the expiratory valve and the crew compartment.

Pressure drop tests on the gas collection assembly valving arrangement were conducted at a measured air flow rate of 400 liters/min.

Differential pressures were measured with aneroid type pressure gauges calibrated in inches of water.

Differential pressure was measured between two sections of equal diameter straight tubing connected at the "input" and "output" of the valve system. Pressure drop due to system connections alone were subtracted from the measurement. Flow rates were achieved in the forward direction (exhale) using pressurized gas.

Results

The results of the forward pressure drop test are as follows:

Flow: 400 l/min (15 cfm)

System pressure drop	=	.3" H_2O
Total pressure drop with valve inserted	=	.4" H_2O
Pressure drop of valve	=	.1" H_2O

12. Leakage Test

Reference - T.P. B202.05 Para. 5.1.9

Date of Test - 20 May 1966

Test Requirement - To test the Pulmonary Collection Assembly for leakage after it has been exposed to all the Design Approval Tests. Results and conditions of test to be recorded after testing.

A differential absolute pressure manometer was attached to the inlet port of the complete pulmonary gas collection assembly. The bag was inflated to .2 psia above the ambient 1 atmosphere pressure with a mixture of 90% oxygen and 10% carbon dioxide. Ambient temperature was maintained at 80°F. and atmospheric pressure monitored to ensure keeping a pressure differential across the walls of the assembly.

A glass wall mercury manometer was used for measurement of both pressure differential and volumetric changes. The atmosphere side of the manometer was movable in the vertical plane in order to maintain a constant pressure as the gas volume in the collection bag side decreased. The volume

leakage versus time was thus obtained from the linear measurement of the rise of mercury in the calibrated bore tube on the collection bag side of the manometer.

Results

The gas collection assembly after successfully meeting the other requirements of the Design Approval Tests, both storage and operational, was subjected to the leakage test, the last test outlined in the B202.05 procedure. After being inflated it was found that the bag leaked in excess of the maximum allowable 100 ml per hour. Since the Endurance test resulted in the bag being subjected to excessive or overstress conditions (refer to Para. No. 6 Endurance Test) it was anticipated that leakage would be found at those points where continuous flexing occurred. Testing indicated that the leakage did occur as expected at these points, namely the base of the outlet port and the base of the inspiratory valve assembly inlet port.

APPENDIX B

QUALIFICATION TEST REPORT FOR PULMONARY COLLECTION ASSEMBLY AND ASSOCIATED EQUIPMENT

QUALIFICATION TEST REPORT
FOR
PULMONARY COLLECTION ASSEMBLY
AND ASSOCIATED EQUIPMENT

Prepared for

National Aeronautics and Space Administration
Manned Spacecraft Center
Houston, Texas

Contract NAS 9-5514

Melpar Job No. 5768

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ABSTRACT

This report summarizes the test procedures and results for Pulmonary Collection Assembly and Associated Equipment items subjected to Qualification tests. These tests were performed to demonstrate the suitability of the items for their intended use, and their ability to withstand selected environmental stresses.

1.0 INTRODUCTION

All test items were subjected to the following test procedure:

a. Pre-environmental acceptance tests.

These tests were divided into two categories:

(1) Operational Configuration

Tests were performed in accordance with T.P. B202.03 to verify conformance to all functional design criteria.

(2) Storage configuration

Tests were performed in accordance with T.P. B202.02 to verify that each item was vacuum-packaged according to specifications.

b. Qualification Tests - Storage Configuration

Tests were performed in accordance with T.P. B202.04 to prove that the Pulmonary Collection Assembly, in the Storage Configuration, is capable of withstanding environmental stresses in accordance with design specifications.

c. Qualification Tests - Operational Configuration

Tests were performed in accordance with T.P. B202.01 to show that the Pulmonary Collection Assembly met specified durability requirements and remained functional after endurance testing.

2.0 QUALIFICATION ENVIRONMENTAL TESTS

The test items were exposed to the following environmental conditions in their storage configuration:

a. High temperature: Temperature 160 $\pm$ 3.6°F, pressure 5 $\pm$ 0.5 psia, for 48 hours.

b. High temperature - Low pressure: Temperature 160 $\pm$ 3.6°F, pressure 1 x 10^{-6} psia, for 1.5 hours.

c. Low temperature: $0 \pm 3.6^{\circ}F$ for a minimum of 4 hours.

d. Temperature - Pressure: Sixteen temperature cycles at a pressure of 1×10^{-6} psia. One temperature cycle is defined as a temperature change from $+160^{\circ}F$ to $0^{\circ}F$ to $160^{\circ}F$ within 90 minutes.

e. Decompression: 1×10^{-6} psia for ten minutes. This test was performed on Gas Collection Assemblies only. After inflating, the assemblies were deflated, refolded and replaced into their overwrap, unsealed. When thus subjected to the environment stated above, the assembly volume may not increase to more than 30 cubic inches.

3.0 QUALIFICATION OPERATIONAL TESTS

The following tests were performed to prove that the Gas Collection Assembly is capable of withstanding all operational requirements.

a. Endurance Test: The units were inflated and deflated at 20 minute intervals in an atmosphere of $160^{\circ}F$ for 48 hours.

b. Folding Resistance: Samples of Gas Collection Assembly material were subjected to 90° folding and twisting at a rate of 9 cycles per minute.

c. Tear Resistance: Samples of Gas Collection Assembly material were subjected to a tear strength test in accordance with ASTM D 1004, "Tear Resistance of Plastic Film and Sheeting".

d. Burst Strength Test: Samples of Gas Collection Assembly material were subjected to a burst strength test, employing an apparatus similar to that used to determine the burst strength of paper as described in ASTM D 774.

e. Leakage Test: The Gas Collection Assembly was inflated to 0.2 psia above ambient pressure with a gas mixture of 90% oxygen, 10% CO_2. Leakage was monitored for 6 minutes. A leakage of more than 100ml/hr constitued a failure.

4.0 TEST RESULTS

Qualification tests were initiated on the following items:

2 each Pulmonary Collection Assemblies - S/N 4 and 5

2 each Nose Clip and Mouthpiece Assemblies-S/N 4 and 5

1 each Breathing Valve - S/N 1

1 each Interconnecting Hose - S/N 2

Due to failures, Pulmonary Collection Assemblies S/N 6, 7 and 43 were substituted at various points of the test procedure.

4.1 Pulmonary Collection Assemblies

4.1.1 Assemblies S/N 4 and 5 passed all phases of acceptance testing, T.P. B202.02 and T.P. B202.03. They were then subjected to the storage configuration environmental tests, T.P. B202.04. During the Temperature-Pressure Test the items failed due to delamination of the overwrap seals. The defective overwraps were submitted to Reliability Engineering for analysis. Based on this analysis the sealing technique was modified to eliminate all material beyond the seal edge by employing a wider seal. Two new assemblies, S/N 6 and 7, were packaged with this new technique and tested.

4.1.2 Assemblies S/N 6 and 7 passed all phases of acceptance testing, T.P. B202.02 and T.P. B202.03. They were

then subjected to the environmental tests, T.P. B202.04 and T.P. B202.01. No failure occured. However, during the leakage test specified in the Operational Configuration Qualification Test Procedure, T.P. B202.01, both assemblies indicated excessive leakage. They were consequently turned over to Reliability Engineering for failure analysis. Assembly S/N 6 was found to have two tears, 1/8" and 1/16" long, at the non-valve end of the bag immediately behind the seam. Assembly S/N 7 had developed a 3/32" tear immediately behind the seal along the inlet valve. The failure of both assemblies is considered to be due to fatigue resulting from repeated inflating and deflating during the endurance test. It has been recommended that this test be reviewed for practicality. A new assembly, S/N 43, was substitued.

4.1.3 Assembly S/N 43 passed all phases of acceptance testing and storage configuration environmental testing. Special precautions were then taken during endurance testing in an effort to determine how many inflation-deflation cycles at 160°F the assembly could successfully withstand. The assembly was tested for 18 hours (54 cycles) and then checked for leakage. No leakage was detected. It was then subjected to another 23 hours of endurance testing (69 cycles) and again checked for leakage. No leakage showed. The assembly was then subjected to another 7

hours of endurance testing (27 cycles) to complete the 48 hour requirement. Subsequent leakage test showed the assembly to be good.

4.1.4 Materials Testing - Samples of the polyethylene material (1.83 mil average thickness), used in the manufacture of Pulmonary Assemblies, were subjected to the tests shown below.

4.1.4.1 Folding Endurance - Samples subjected to "Twist-Flex" action at the rate of nine cycles per minute showed no defects after the total number of cycles shown below:

Parallel to machine direction,

3 samples tested - 150 cycles

Transverse to machine direction,

3 samples tested - 125 cycles

3 samples tested - 100 cycles

Note: The machine direction is defined as the direction the material was pulled from the rollers while being manufactured.

4.1.4.2 Burst Strength: Five samples were subjected to this test. The lowest burst strength encountered was 9.2 lbs/in^2, the highest was 9.5 lbs/in^2, the average was 9.34 lbs/in^2.

4.1.4.3 Tear Strength - Ten samples were subjected to this test in the parallel and transverse

direction. Average tear strength in the direction paralled to the machine direction was 0.77 lb. Average tear strength in the direction transverse to the machine direction was 1.18 lb.

4.2 Nose Clip and Mouthpiece Assemblies

Assemblies S/N 4 and 5 passed all phases of acceptance testing, T.P. B202.02 and T.P. B202.03. They were then subjected to the storage configuration environmental tests, T.P. B202.04. During the Temperature-Pressure test both units failed due to delamination of the overwrap seals. Failure analysis and corrective action were performed as in paragraph 4.1.1. The same two assemblies were repackaged employing the new sealing technique. Storage configuration acceptance tests and environmental tests were repeated. The overwrap seal of Assembly S/N 5 again indicated some leakage. It was resubmitted to Reliability Engineering for analysis. Assembly S/N 4 showed no failures during environmental testing.

4.3 Breathing Valve

Unit S/N 1 passed all phases of acceptance testing, T.P. B202.02 and T.P. B202.03. It was then subjected to the storage configuration environmental test, T.P. B202.04 during which the overwrap seal delaminated, constituting a failure. Failure analysis and corrective

action were performed as in paragraph 4.1.1. The unit was repackaged employing the new sealing technique. Storage configuration acceptance tests and environmental tests were repeated. The unit showed no failures at any time.

4.4 Interconnecting Hose

Unit S/N 2 passed all phases of acceptance testing, T.P. B202.02 and T.P. B202.03. It was then subjected to the storage configuration environmental test, T.P. B202.04 during which the overwrap seal delaminated, constituting a failure. Failure analysis and corrective action were performed as in 4.1.1. The unit was repacked, employing the new sealing technique. Storage configuration acceptance tests and environmental tests were repeated. The unit showed no failures at any time.